



# UNITED STATES PATENT AND TRADEMARK OFFICE





UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/769,439	01/26/2001	Richard L. Verrier	1565.0020002	4394		
26111	7590 02/26/2003					
STERNE, KESSLER, GOLDSTEIN & FOX PLLC			EXAMINER			
	ORK AVENUE, N.W., SU ON, DC 20005-3934	LAM, ANN Y				
			ART UNIT	PAPER NUMBER		
		3763				
			DATE MAILED: 02/26/2003			

Please find below and/or attached an Office communication concerning this application or proceeding.

							S			
Offic Action Summary			Applicati r	N.	Applicant(s)					
				09/769,439		VERRIER ET AL.				
			Examiner		Art Unit					
				Ann Y. Lam		3763				
	The MAILING DATE of this communication app ars on the cov r she t with the correspondence address									
Period for Reply										
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status										
1)⊠	Respons	ive to communication(s) fi	led on <u>16 De</u>	ecember 20	<u>002</u> .					
2a) <u></u> □	This action	on is FINAL.	2b) This	s action is r	on-final.					
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.									
Disposition of Claims										
,		<u>30-47,49,50,55-59,61-64</u>				•				
	4a) Of the above claim(s) is/are withdrawn from consideration.									
5) Claim(s) is/are allowed.										
•	' ' -	<u>0-47,49,50,55-59,61-64 a</u>	<u>nd 66-71</u> is/	are rejecte	d.					
		is/are objected to.								
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers										
9)☐ The specification is objected to by the Examiner.										
10) 🗌 🗆		g(s) filed on is/are:								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).										
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.										
If approved, corrected drawings are required in reply to this Office action.										
12) The oath or declaration is objected to by the Examiner.										
		.S.C. §§ 119 and 120			05.11.0.0.0.440	(A) (A) = 4 (O				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).										
a) All b) Some * c) None of:										
	1. Certified copies of the priority documents have been received.									
2. Certified copies of the priority documents have been received in Application No										
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>										
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).										
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.										
Attachment(s)										
2) Notice	e of Draftspe	es Cited (PTO-892) rson's Patent Drawing Review (F sure Statement(s) (PTO-1449) P			4) Interview Summa 5) Notice of Informa 6) Other:	ry (PTO-413) Paper No I Patent Application (PT				

Application/Control Number: 09/769,439

Art Unit: 3763

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 30-36, 45-47, 49, 50, 55, 56, 61-63 and 66-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al., 5,941,869.

As to claim 30, Patterson et al. discloses a guide catheter (58); an infusion guide wire (50) coaxial with said guide catheter; and a leading guide wire (56) coaxial with said infusion guide wire and having a diameter sufficiently small to be passed through a lumen of said infusion guide wire, said leading guide wire having a sufficient length to pass through and protrude from a distal end of said infusion guide wire, and having a distal end capable of penetrating a wall of the right atrium of a subject's heart, wherein both guide wires having sufficient flexibility to permit them to be simultaneously passed

Art Unit: 3763

through said guide catheter into the right atrium of the subject's heart via a transvenous route, see column 6, line 65 – column 7, line 9.

As to claim 31, said infusion wire has a diameter as claimed, see column 7, lines 1-6.

As to claim 32, said guide catheter has length and flexibility as claimed, see column 7, lines 1-6.

As to claim 33, said infusion guide wire has flexibility as claimed, see column 7, lines 1-6.

As to claims 34, 36, said infusion guide wire functions as an aspiration catheter and has a lumen with a diameter as claimed, see column 7, lines 6-9.

As to claim 35, said leading guide wire has flexibility as claimed, see column 7, lines 1-6.

As to claim 45, the leading guide wire is steerable to any location within the pericardium, see column 7, lines 1-6.

As to claim 46, the kit is adapted to perform a surgical procedure on the heart, see column 7, lines 1-6.

As to claim 47, the kit is adapted for placing an implantable device into the pericardium, see column 7, lines 6-9.

As to claims 49, 66-70, the infusion guide wire and leading guide wire jointly have the pushability as claimed, see column 7, lines 1-6.

As to claims 50, 61, 62, the infusion guide wire has a lumen with a diameter as claimed, see column 7, lines 1-6.

Application/Control Number: 09/769,439

Art Unit: 3763

As to claims 55, 56,the dual guide wire has flexibility without kinking as claimed, see column 7, lines 1-6.

As to claim 63, said infusion guide wire is coaxial with the guide catheter as claimed, see Figure 1, and column 12, line 56 – column 13, line 12.

As to claim 71, the dual guide wire is adapted for implantation as claimed, see column 12, line 56 – column 13, line 12.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al., 5,941,869.

Patterson et al. discloses the invention substantially as claimed, except for the leading guide wire having a diameter as claimed. However, it would have been obvious to one of ordinary skill in the art to provide a leading guide wire having the claimed diameter as would be necessary to perform a surgical procedure on a patient having an anatomical passageway of a particular size,

3. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al., 5,941,869, in view of Helmus et al., 5,569,197.

Application/Control Number: 09/769,439

Art Unit: 3763

Patterson et al. discloses the invention substantially as claimed, see above, except for the leading guidewire being hollow.

Helmus et al. teaches a hollow guidewire (20) for drug delivery, see column 4, lines 18-29. Helmus et al. also teaches that the hollow guidewire may be used with a catheter, see column 2, lines 55-65. It would have been obvious to use a hollow guidewire as taught by Helmus et al. with the Patterson et al. catheter and sheath in order to guide the catheter and sheath and to deliver drugs, as taught by Helmus et al..

4. Claims 42-44, 57-59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al., 5,941,869, in view of Mottola et al. 5,957,901.

Patterson et al. discloses the invention substantially as claimed, see above, except for a radiopaque marker as claimed.

Mottola et al. discloses a catheter with a radiopaque marker in order to provide the user with means for positioning the device at a desired location, see column 4, lines 4-7. It would have been obvious to provide a radiopaque marker on the Patterson et al. catheter, infusion guidewire or leading guidewire, in order to provide means for positioning the device, as taught by Mottola et al.

### Response to Arguments

Applicant's arguments filed August 2, 2002 with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Application/Control Number: 09/769,439 Page 6

Art Unit: 3763

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

February 21, 2003

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700